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Sterling Medivations, Inc.
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510(k) SUMMARY

Date Submitted: September 14, 2001

Submitter: Sterling Medivations, Inc. 25285 La Loma Drive, Los Altos Hills, CA 94022 Company Phone 650-949-0470, Company fax 650-949-0

Contact: Joel Douglas, Chief Technology Officer
Sterling Medivations, Inc.
Applicant Phone 650-949-0470, Applicant Fax 650-949-0342

Trade Name of Device: Simplicity™ QD Soft Infusion Set for use by people with diabetes to infuse insulin subcutaneously from a pump or syringe.

Common Name of Device: Intravascular administration set.

Classification Name: Percutaneous intravascular catheter.

Predicate Device: The predicate device for Sterling's Simplicity™ QD Soft Infusion set is the Sterling Medivations Simplicity™ Silver Soft Infusion, K010846.

Description of the New Device: Sterling Medivations, Inc.'s ("SMI") Simplicity ™ QD Soft Infusion Set is designed for use by people with diabetes to infuse insulin subcutaneously from a pump or syringe.

The Simplicity ™ QD Soft Infusion Set proposed for commercial distribution is similar in all significant respects to the existing Sterling Medivations Simplicity Silver Soft Infusion, K010846 and it has the same intended use.

The device consists of four main parts: (1) an infusion catheter made from Fluorinated Ethylene Propylene (FEP), (2) an infusion hub that provides the patient the capability of disconnecting the connecting tube from the infusion catheter, (3) a connecting tube and (4) a female Luer connector.

The Simplicity QD Soft Infusion Set is an infusion administration set, connecting to a pump or syringe and inserted in the subcutaneous tissue of a patient. The Sterling Medivations Simplicity QD Soft Infusion Set may be used with any infusion device that delivers continuous or intermittent flow.

The administration set attaches to the pump or syringe by means of a female Luer connector, and subcutaneously in the patient through an indwelling catheter made of Fluorinated Ethylene Propylene (FEP). The connecting tubing is made from a polyethylene tube.

The 25 gauge-indwelling FEP catheter is introduced into the subcutaneous tissue using an insertion needle. The insertion needle is removed and a connector housing is attached to the hub fixed to the indwelling catheter. This connector needle part of the connector hub pierces a septum forming a seal that permits the infusion of medication without leakage. The connector needle is connected to the connecting tubing and a connector housing. The connector tubing proximal end is attached to a female Luer connector for attachment to the medicine reservoir. The connecting tube is solvent bonded to the connector housing and to the Luer connector. The quick disconnect allows the patient to temporally disconnect the pump reservoir from the indwelling catheter to better facilitate bathing and reservoir changes.

Intended Use of the New Device: The intended use of the Simplicity QD Soft Infusion Set is to provide a means to infuse or inject insulin subcutaneously when the device is attached to a pump or syringe

Comparisons of the Technological Features of the New Device and Predicate Device:

The Simplicity QD Soft Infusion Set proposed for commercial distribution is similar in all significant respects to the existing Sterling Medivations Simplicity Silver Soft Infusion 510(k) K010846.

The materials and manufacturing processes are substantially equivalent, the labeling is substantially equivalent to the Sterling Medivations Simplicity Silver Soft Infusion, FDA 510(k) K010846.

The differences that exist between the new and predicate device are as follows:

1) The Simplicity QD Soft Infusion Set indwelling catheter is bonded to the hub with Loctite 322. The predicate device has an indwelling catheter which is press fit into the hub and sealed with Loctite 4011.

2) The Simplicity QD Soft Infusion Set has a septum made of Silicone - ELASTOSIL ® R 401/40. The predicate device has a plug made of Silicone - ELASTOSIL ® R 401/40.

3) The Simplicity QD Soft Infusion Set has a septum in the infusion hub for injecting with a syringe. The predicate device has a septum in the plug cover for injecting with a syringe.

Performance Data Supporting Substantial Equivalence: To provide substantial equivalence the Simplicity QD Soft Infusion Set meets the catheter requirements of:

CDRH 21 C.F.R. section 880.54400 Intravascular administration set,
ISO 10555 Sterile, single use intravascular catheters (Part 1: General Requirements), and
ISO 10555 Sterile, single use intravascular catheters (Part 5: peripheral catheters).,
ISO 9626 Stainless steel needle tubing for the manufacture of medical devices,
ISO 11135: 1994 Medical devices – Validation and routine control of ethylene oxide sterilization,
ISO 11138-2:1994 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization.
ISO 594-1: 1986 Conical fittings with a 6%)Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements,
ISO 594-2: 1998 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings,
ISO 11607: 1997 Packaging for terminally sterilized medical devices,
ISO 8537: 1991 Sterile single use syringes, with or without needle for insulin,
ISO 11135: 1994 Medical devices – Validation and routine control of ethylene oxide sterilization,
ISO 11138-2: 1994 Sterilization of health care products – Biological indicators – Part 2:Biological indicators for ethylene oxide sterilization.

FDA Guidelines on validation of the Limulus Amebocyte Lysate (LAL) Test as an end-product endotoxin test for human and animal parenteral drugs, biological products, and medical devices. ODE Blue Book Memorandum #K90-1.

The design process adhered to is the Center of Devices and Radiological Health. DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS. This Guidance relates to FDA 21 CGR 820.30 and Sub-clause 4.4 of ISO 9001. This is substantially equivalent to the predicate device.

Signed

Joel S. Douglas
Chief Technology Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Joel Douglas
Chief Technology Officer
Sterling Medivations, Incorporated
25285 La Loma Drive
Los Altos Hills, California 94022-4583

Re: K013104
Trade/Device Name: Simplicity QD Soft Infusion Set
Regulation Number: 880.5440
Regulation Name: Intravascular Adminstration Set
Regulatory Class: II
Product Code: FPA
Dated: September 14, 2001
Received: September 17, 2001

Dear Mr. Douglas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013104

Device Name: Simplicity QD Soft Infusion Set

Indications For Use:

The intended use of the Simplicity QD Soft Infusion Set is to provide a means for infusion and/or injection of fluids into the body below the surface of the skin when attached to an external pump or syringe.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(PER 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cuseiste

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013104